SEP - 6 2005

K05 2005

510(k) Summary
R&R External Fixator System

Date	July 20, 2005
Submitter	R&R Medical, Inc. 2225 Park Place Drive Slatington, Pa. 18080
Contact person	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199
Trade Name	R&R External Fixation System
Common name	External fixation frame
Classification name	Single/multiple component metallic bone fixation appliances and accessories Class II per 21 CFR section 888.3030
Product Code	KTT
Equivalent Device	True/Lok Monolateral/Bilaterial (Applied Osteo Systems, K941048) DFS® MiniFixator (EBI, K951357/K970290) Small Bone External Fixation System (Acumed)

Device Description

The R&R Ring Fixator assembly consists of three basic types of elements: 1) bone anchorage elements, 2) bridge elements, and 3) connection elements. The Ring Fixator design allows freedom of pin placement, ease of assembly and stable fixation of bone fragments with the possibility of axial loading of the extremity and immediate range of motion of all adjacent joints.

Bone anchorage elements include pins and wires. Bridge elements include rings or arches and extensions. Connection elements include struts, nuts and bolts, wire fixation bolts and pin clamps.

The R&R Unilateral Mini Fixator is a stable solution for fractures and for lengthening of small bones. The system allows precise, controlled compression / distraction and early weight bearing. The articulating pin clamps allow adjustment around three axes and linear translation so that it can be used for comminuted intra-articular fractures, joint stiffness, or arthrodesis of the foot or hand. The fixator design enables pins to be located in multi-planar arrangements, allowing the frame to be built around the fractures in the hand or foot.

Intended Use

The R&R Ring Fixator and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction or bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The R&R Ring Fixator is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

The R&R Unilateral Fixator is indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

R & R Medical, Inc.
c/o J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K052005
Trade/Device Name: R & R External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 20, 2005
Received: July 25, 2005

Dear J.D. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: R&R External Fixation System

Indications for Use:

The R&R Ring Fixator and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction or bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The R&R Ring Fixator is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

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Prescription Use __X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052005